

CLAIMS

We claim:

1. An osmotic device comprising:

5 a core comprising a first amount licofelone and at least one osmotic agent or
osmopolymer;

a semipermeable membrane surrounding the core and having at least one
passageway there through; and

optionally, a drug-containing water soluble and/or erodible coat comprising a
second amount of licofelone;

10 wherein at least 75% of the licofelone is released within 24 hours after exposure of the
osmotic device to an aqueous environment, and wherein the first and second amounts
together comprise a therapeutically effective amount suitable for once daily
administration to a subject.

2. The osmotic device of claim 1, wherein: 1) at least 10% of the licofelone is
15 released from the core within 4 hours; 2) at least 45% of the licofelone is released from
the core within 12 hours; 3) at least 60% of the licofelone is released from the core within
16 hours; and 4) at least 75% of the licofelone is released from the core within 20 hours
after exposure of the osmotic device to an aqueous environment.

3. The osmotic device of claim 1, wherein: 1) 20-30% of the licofelone is
20 released within about 1 hours; 2) 25-65% of the licofelone is released within about 4
hours; 3) 47-83% of the licofelone is released within about 12 hours; and 4) at least 75%
of the licofelone is released within about 24 hours after exposure of the osmotic device to
an aqueous environment.

4. The osmotic device of any one of claims 1, 2 or 3, wherein the drug-
25 containing coat is present, further comprising an inert water soluble and/or erodible coating
disposed between the semipermeable membrane and the drug-containing coating.

5. The osmotic device of claim 4, wherein the drug-containing coat is sprayed
onto the inert coating.

6. The osmotic device of claims 1 or 2 wherein the licofelone is released from the core according to a first order or pseudo-first order rate for a period of at least 12 hours.

7. The osmotic device of claim 4 wherein the licofelone is released from the core according to a first order or pseudo-first order rate for a period of at least 12 hours.

8. The osmotic device of claims 1 or 2 wherein the licofelone is released from the core according to a zero order or pseudo-zero order rate for a period of at least 12 hours.

9. The osmotic device of claim 4 wherein the licofelone is released from the core according to a zero order or pseudo-zero order rate for a period of at least 12 hours.

10. The osmotic device of claims 1 or 2 wherein the licofelone is released from the core according to a sigmoidal release profile.

11. The osmotic device of claims 4 wherein the licofelone is released from the core according to a sigmoidal release profile.

12. The osmotic device of claim 4, wherein the drug-containing coat is present in an amount of at least about 25% wt. based upon the total weight of the osmotic device.

13. A method of treating a condition in a subject, the condition being responsive to treatment with licofelone, the method comprising the step of administering to the subject once per day an osmotic device according to any one of claims 1-12.

14. The method of claim 13, wherein the condition is selected from the group consisting of osteoarthritis, rheumatoid arthritis, an inflammation related disorder, spondyloarthropathies, gouty arthritis, osteoarthritis, systemic lupus erythematosus and juvenile arthritis, asthma, bronchitis, menstrual cramps, tendinitis, bursitis; skin related conditions such as psoriasis, eczema, burns and dermatitis; gastrointestinal conditions such as inflammatory bowel disease, Crohn's disease, gastritis, irritable bowel syndrome and ulcerative colitis; for the prevention or treatment of cancer, such as colorectal cancer; inflammation in vascular disease, migraine headache, periarteritis nodosa, thyroiditis, aplastic anemia, Hodgkin's disease, sclerodoma, rheumatic fever, type I diabetes, myasthenia gravis, multiple sclerosis, sarcoidosis, nephrotic syndrome, Behcet's syndrome, polymyositis, gingivitis, hypersensitivity, swelling occurring after injury,

myocardial ischemia, viral infections and cystic fibrosis; central nervous system disorders such as cortical dementias including Alzheimer's disease; allergic diseases; allergic rhinitis; respiratory distress syndrome; endotoxin shock syndrome; atherosclerosis; and central nervous system damage resulting from stroke, ischemia and trauma.